



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,801	10/16/2003	Shibnath Ghosal	4822-129 US	7933
26817 7590 01/07/2009 MATHEWS, SHEPHERD, MCKAY, & BRUNEAU, P.A. 29 THANET ROAD, SUITE 201 PRINCETON, NJ 08540				
EXAMINER				
WEBB, WALTER E				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
01/07/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/686,801

Applicant(s)

GHOSAL, SHIBNATH

Examiner

WALTER E. WEBB

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 5-11, 13-22, 24-27, 30-34, 36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-11, 13-22, 24-27, 30-34, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments, filed 9/15/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

Claims 1, 2, 5-11, 13-22, 24-27, 30-34, 36 and 37 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ghosal ('436), and Pushpangadan et al., and in further view of Boynton et al.

Applicant argues Pushpanagan teaches away from using *Shilajit* and *Phyllanthus emblica* since it states that "Most of the products are a mixture of herbs/medicinal plants, minerals, and bhasams (ashes) without a suitable balanced nutritional composition to ameliorate the general health of diabetics and none of them is a nutraceutical." However, this does not necessarily teach away from use. One could use these products to ameliorate the general health of diabetics if a suitable balanced nutritional composition is added. Furthermore, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In this case, Pushpanagan was used to show that herbal health compositions can be used to control blood sugar levels in patients with diabetes, and that commercial herbal anti-diabetic products containing *Shilajit* and *Phyllanthus emblica* are available.

Applicant argues that the present invention satisfies a long felt but unsolved need, since it provides a composition for treating diabetes or glucose tolerance by employing a safe and effective phenolic antioxidant-chromium complex, without pro-oxidation activity. In regard to establishing a long-felt need MPEP 716.04 states:

Establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. The relevance of long-felt need and the failure of others to the issue of obviousness depends on several factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. *In re Gershon*, 372 F.2d 535, 539, 152 USPQ 602, 605 (CCPA 1967) ("Since the alleged problem in this case was first recognized by appellants, and others apparently have not yet become aware of its existence, it goes without saying that there could not possibly be any evidence of either a long felt need in the . . . art for a solution to a problem of dubious existence or failure of others skilled in the art who unsuccessfully attempted to solve a problem of which they were not aware."); *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 217 USPQ 1281 (Fed. Cir. 1983) (Although the claimed invention achieved the desirable result of reducing inventories, there was no evidence of any prior unsuccessful attempts to do so.).

Second, the long-felt need must not have been satisfied by another before the invention by applicant. *Newell Companies v. Kenney Mfg. Co.*, 864 F.2d 757, 768, 9 USPQ2d 1417, 1426 (Fed. Cir. 1988) (Although at one time there was a long-felt need for a "do-it-yourself" window shade material which was adjustable without the use of tools, a prior art product fulfilled the need by using a scored plastic material which could be torn. "[O]nce another supplied the key element, there was no long-felt need or, indeed, a problem to be solved".)

Third, the invention must in fact satisfy the long-felt need. *In re Cavanagh*, 436 F.2d 491, 168 USPQ 466 (CCPA 1971).

In regard to the first prong of the test, applicant provides no evidence that the need was "a persistent one that was recognized by those of ordinary skill in the art." Because the

first prong is not satisfied, the test for long-felt need fails. Accordingly, applicant's argument is unpersuasive.

Applicant also argues that the composition has an unexpected aspect in that the antioxidant ligand for chromium is capable of occupying all the available sites in chromium, thereby eliminating the possibility of forming undesirable oxochromium complex. However, the instant claims are inclusive of partial complexes, so occupying all the binding sites are not required to meet the claimed subject matter. If the property is unexpected applicant has not factually demonstrated this. Similarly, even if it was factually demonstrated, the claims would not be commensurate in scope because they are not limited to complexes in which all available sites are bound.

Applicant also argues that the amount of Chromium disclosed in Boynton et al., cannot be adjusted through routine experimentation. However, Boynton teaches that the recommended intake of chromium is 50-200 micrograms daily. (See col. 5, lines 36-39.) This states the general conditions in regard to chromium intake and allows for adjustments to be made by the artisan. This range overlaps with applicants range at claim 7, and therefore establishes a *prima facie* case of obviousness.

Nonstatutory Obvious-type Double Patenting

Claims 1, 5, 9-11, 13-16, 18, 20, 31, 33, 36 and 37 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of Ghosal ('436) and claim 1 of Ghosal ('612)

Applicant argues that the Examiner gave not explanation or evidence why the extract is the same extract of the fruit of *Eblica officianalis*. However, it was stated previously that the extracted product, oxygenated dibenzo-a-pyrone (DBPs), is the same regardless of the source and as such, the oxygenated DBPs from Shilajit are the same as the oxygenated DBPs from *Emblica officinalis*.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb
/Walter E Webb/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612